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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,858	10/31/2003	Gary T. Seim	GUID.014US01	9341

51294 7590 07/21/2010

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EXAMINER	
HOLMES, REX R	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
07/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,858	SEIM ET AL.	
	Examiner	Art Unit	
	REX HOLMES	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,13-15,18,20,21,29,30,33,36,39-41,48-50,53,55,58,60,63 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,4,6,13-15,18,20,21,29,30,33,36,39-41,48-50,53,55,58,60,63 and 64.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/30/10 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 13-15, 18, 20, 33, 36, 39, 48-50, 53, 55, 60 and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klepfer et al. (U.S. Pub. 2005/0038478 hereinafter "Klepfer") in view of Warren et al. (U.S. Pub. 2002/0068959 hereinafter "Warren") in view of Levine et al. (U.S. Pat. 7,031,773 hereinafter "Levine").

Klepfer discloses an Anti-tachycardia Pacing therapy that checks to see if a beat is an abnormal evoked response, if so it then checks for a lead related condition and if a condition is found it disables the ATP therapy (e.g. ¶¶80, 85, 111; Fig. 6). Klepfer discloses the claimed invention including that the lead related condition is checked using the impedance (e.g. ¶¶80, 85, 111). Klepfer further discloses that when the ATP therapy is disabled the system it adjusts the therapy (e.g. ¶85). Klepfer further discloses that one of the many therapies available in the system are non-atrial tracking pacing therapies such as VVI and DDI therapies (e.g. ¶ 59, Claims 12 and 22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the therapy that the system switches to after ATP therapy as taught by Klepfer e.g. ¶85, with one of the other therapies as disclosed by Klepfer that does not require an atrial sensing lead, since such a modification would provide the predictable results of switching the therapy from one that requires an atrial lead to another therapy that does not require an atrial lead for providing stimulation to the heart after the device withholds ATP therapy due to atrial lead failure.

5. Klepfer further disclose that the system that communicates with an external device and further automatically adjusts the therapy when the ATP therapy is disabled to utilize leads that are not experiencing a lead related condition, however Klepfer does

not disclose manually switching therapies. However, Warren discloses a capture based lead system that allows for the physician to monitor and manually set the electrodes and the activation (e.g. Paragraphs 8, 15-16 and 18-19) in order to adjust the therapy based on the specific needs of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Klepfer, with a system that manually switches the therapy since it was known in the art that a system can be manually adjusted to provide the predictable results of allowing a physician to adjust the therapy based on the specific needs of the patient.

6. Klepfer discloses the claimed invention as discussed above, but Klepfer does not expressly disclose that it uses an impedance threshold developed for the particular patient or the exact method in which it determines if there is a lead related condition.

7. Levine et al. disclose measuring an impedance of an atrial lead (e.g., column 11, lines 5 and 7–10; column 13, lines 52–53; column 14, lines 21–23); comparing a measured impedance with an impedance threshold developed for a particular patient (e.g., column 11, lines 11–15; column 8, last line–column 9, lines 1–2; column 13, lines 59–60); disabling atrial ATP therapy delivery in response to a measured impedance deviating from an impedance threshold by a predetermined factor (e.g., column 11, lines 11–19 wherein the step of switching the electrode configuration to an electrode configuration other than the current electrode configuration represents disabling atrial ATP therapy delivery to the electrode configuration previously receiving the therapy); measuring a capture threshold (e.g., column 12, lines 26–28), and a sense amplitude

(evoked response) (e.g., column 7, lines 59 and 65; column 10, lines 12–13 and 28–30) (claims 20, 55, and 62); comparing capture threshold, and sense amplitude measurements with capture threshold, and sense amplitude limits, respectively (e.g., column 10, lines 35–55) (claims 20, 55, and 62); an implantable housing (e.g., Fig. 1); detection circuitry (e.g., Fig. 2); energy delivery circuitry (e.g., Fig. 2); a lead system respectively coupled to a detection and energy delivery circuitry, a lead system comprising at least an atrial lead (e.g., Figs. 1–2) and a control system provided in a housing and coupled to memory within which an impedance threshold developed for a particular patient is stored (e.g., Fig. 2) (claim 36).

8. Levine et al. further discloses an impedance threshold is developed from a single atrial lead impedance measurement (claims 2, 26, and 37) and a plurality of atrial lead impedance measurements (claims 3, 27 and 38) (e.g., Fig. 3; column 11, lines 11–15); wherein measuring an impedance of an atrial lead comprises taking a plurality of impedance measurements to characterize an impedance of an atrial lead (claims 9 and 44) (e.g., Fig. 3, elements 208 and 220); measuring an impedance of an atrial lead comprises taking a single impedance measurement to characterize an impedance of an atrial lead (claims 10 and 45) (e.g., column 13, lines 52–53); a predetermined factor is characterized by a percentage change in a measured impedance relative to an impedance threshold (claims 11, 31 and 46) (e.g., column 11, lines 10–15) and a fixed delta change (500 ohms) in the measured impedance relative to the impedance threshold (claims 12, 32 and 47) (e.g., column 11, lines 13–14) and both a percentage change and a fixed delta change in the measured impedance relative to the impedance

threshold (claims 13, 33 and 48) (e.g., column 11, lines 10–15 and 13–14); measuring an impedance comprises delivering a pace pulse via an atrial lead and deriving an impedance measurement using a delivered pace pulse (claims 14 and 49) (e.g., Fig. 3; column 12, lines 7–14) and using a delivered stimulus, a stimulus having an energy insufficient to effect atrial capture (claims 15 and 50) (e.g., Fig. 3; column 12, lines 22–30); an impedance is measured after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery (claims 16, 34 and 51) (e.g., Fig. 3; column 12, lines 9–25); an impedance is measured after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery (claims 17, 35 and 52) (e.g., Fig. 3; column 12, lines 31–37); measuring an impedance comprises taking a plurality of impedance measurements after detection of an atrial arrhythmic event (claims 18 and 53) and after an atrial arrhythmic episode is declared (claims 19 and 54) and prior to atrial ATP therapy delivery (e.g., Fig. 3; column 12, lines 9–25); disabling ATP therapy delivery comprises, upon detection of an atrial arrhythmia, ignoring a capture threshold and sense amplitude deviations (claims 25 and 60), and disabling ATP therapy in response only to the measured impedance deviating from the impedance limit by the predetermined factor (claims 24, 25, 59, and 60) (e.g., Fig. 3; column 12, lines 31–37); an impedance threshold is capable of being characterized by a mean or a median of a plurality of atrial lead impedance measurements (claim 39) because a variance from a previous measurement by some other suitable value (e.g., as shown in column 12 lines 18–21), for example, a mean or median value, is commonly used in an impedance measurement system to measure lead impedance. Levine further discloses that the

system includes a telemetry system to transmitting warnings to and external device and further receiving commands from and external device (e.g. Col. 11, ll. 1-9).

9. Regarding claims 1, 13-15, 18, 20, 33, 36, 39, 48-50, 53, 55, 60, 63-64, Klepfer in view of Warren discloses a method for performing a lead condition test during ATP therapy that includes checking to see if a beat is abnormal evoked response, if so it then checks for a lead related condition using impedance and if a condition is found it disables the ATP therapy, but fails to expressly disclose that it uses a impedance threshold developed for the particular patient. However, Levine et al. discloses a system for determining a lead related condition by measuring impedance using a threshold and further using the system as disclosed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Klepfer in view of Warren, with lead condition system that utilizes thresholds as taught by Levine, since such a modification would provide the predictable results of using impedance measurements along with patient specific thresholds to determine lead related conditions in order to control therapy in the event of a lead related condition.

10. Claims 4, 6, 21, 29–30, 40–41, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klepfer in view of Warren in view Levine et al. (U.S. Pat. 7,031,773).

11. Regarding Claims 4, 6, 29–30 and 40–41 Klepfer in view of Warren in view Levine et al. disclose the essential features of the claimed invention as discussed above except for an impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements (claims 4 and 39) and by an atrial lead

impedance measurement taken immediately before a currently measured impedance (claims 5, 28 and 40) and at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement (claims 6, 29, and 41); and a predetermined amount of time is about one day (claims 7, 30 and 42) and more than one day (claims 8 and 42). However, it is well known in the art to characterize an impedance threshold as set forth in the claim limitations stated herein because they indicate relative displacement of the implanted cardiac lead giving the physician viable information to initiate definitive therapy at the appropriate time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Klepfer in view of Warren in view Levine et al. to include an impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements and by an atrial lead impedance measurement taken immediately before a currently measured impedance and at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement; and a predetermined amount of time is about one day and more than one day to provide the predictable results of a device that allows for delivery of optimal and efficient therapy in a timely manner.

12. Regarding claims 21 and 58, Klepfer in view of Warren in view Levine et al. disclose the claimed invention as discussed in claim 20 above but does not disclose expressly detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the

impedance, capture threshold, and sense amplitude as taught by Levine et al. (e.g., as discussed in the rejection for claim 20 above), to detect an ambiguity, because Applicant has not disclosed that detecting an ambiguity provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the impedance, capture threshold, and sense amplitude as taught by Klepfer in view of Warren in view Levine et al., because they indicate relative displacement of the implanted cardiac lead giving the physician viable information to initiate definitive therapy at the appropriate time and provide a device that allows for delivery of optimal and efficient therapy in a timely manner. Therefore, it would have been an obvious matter of engineering design choice to modify the impedance, capture threshold, and sense amplitude to obtain the invention as specified in the claims.

Response to Arguments

13. Applicant's arguments with respect to claims 1-61 have been considered but are moot in view of the new ground(s) of rejection. Regarding the Klepfer reference the Applicant argued that it failed to teach switching to a non-atrial tracking pacing therapy. As noted above, a couple of the many therapy modes taught by the Klepfer reference are non-atrial tracking modes. Klepfer teaches disabling ATP therapy and changing the mode. Therefore It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Klepfer to change the mode to one of the many available non-atrial tracking modes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./ /George R Evanisko/

Examiner, Art Unit 3762 Primary Examiner, Art Unit 3762